

REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

- I. Claims 40-42 are rejected under 35 USC § 112 ¶ 2 as allegedly being indefinite because certain claim elements are allegedly vague.
- II. Claims 40-42 are rejected under 35 USC § 103(a) as allegedly unpatentable over United States Patent 4,753,246 to Freeman.
- III. Claim 40 is provisionally rejected under 35 USC § 101 for double patenting as allegedly claiming the same invention as that of claim 49 in copending Application No. 10/193,735.

I. The Claims Are Definite

The Examiner asserts that “The claims as written are ambiguous because they do not clearly set forth Applicant’s claimed invention. In particular ... ‘determining an electrotherapeutic drug effect’ ... ‘at least one multivariate out[come] measurement’ ... ‘neurophysiologic information’ ... ‘abnormal electroencephalogram’ ... [and] ... ‘comparing said abnormal information with said follow-up information under conditions such that ... changed’ “. *Office Action pg 4-5 ¶ 6*. The Applicants disagree because these terms and phrases are all clearly explained within the Applicants’ specification:

Claims of a patent application 'are to be construed in the light of the specification and the understanding thereof by those skilled in that art to whom they are addressed'.

Application of Salem, 553 F.2d 676, 683, 193 USPQ 513 (CCPA 1977) (quoting *In re Myers*, 410 F.2d 420, 425 (CCPA 1969).

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 40 to recite: i) “drug efficacy” (*Applicants’ Specification pg 35 ln 11-pg 36 ln 9*) instead of “electrotherapeutic drug effect”; ii) “first”

instead of “abnormal” (*Applicants’ Specification pg 34 ln 18-23*) and “follow-up” is concomitantly changed to “second”; iii) multivariate outcome measurements as “derived from a frequency band selected from the group consisting of delta, theta, alpha, and beta” (*Applicants’ Specification pg 11 ln 8-10*), iv) replacing “neurophysiologic information” with “electroencephalogram” (*Applicants’ Specification pg 7 ln 17-19*); and v) replacing “differentially changed” with “wherein a difference is identified” (*Applicants’ Specification pg 12 ln 11-13*). Further Claim 41 has been voluntarily amended to recite “comprising using” in regards to the reference database. The Applicants believe that none of these amendments substantially alter the original claim scope.

The Examiner is requested to note the addition of four new claims (Claims 50-53) reciting the univariate measurements “absolute power”, “relative power”, “coherence”, and “symmetry” comprised within the frequency bands (*Applicants’ Specification pg 11 ln 10-14; pg 12 ln 30 – pg 13 ln 1*). Also, three other new claims (Claims 54-56) recite an independent claims set directed to deriving univariate measurements within a frequency range of 0.5 – 35 Hertz. (*Applicants’ Specification pg 11 ln 8-9*). Further, four other new claims (Claims 57-60) recite an independent claim set directed to determining drug efficacy using a “symptomatic behavioral assessment”. (*Applicants’ Specification pg 47 ln 20-26*). These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the rejection.

II. The Claims Are Not *Prima Facie* Obvious Over Freeman

The Examiner cites United States Patent 4,735,246 To Freeman as a single reference in support of an obviousness rejection. The Applicants argue that the Examiner has not presented a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that

if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criteria. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

A. Freeman Does Not Teach All the Elements

1. Delta, Theta, Alpha, And Beta Frequency Bands Are Absent

Freeman preferably analyzes frequency bands that are well above those presented in the Applicants' claimed embodiment¹. For example:

It should be noted here that the temporal frequencies of greatest interest are generally in the 30-60 Hz range.

Freeman col 5 ln 54-56, and

... the frequency of the dominant component is between about 60-70 Hz. ... the next dominant frequency component ... having a frequency of about 40 Hz. The FIG. 4A signal was decomposed in this manner to yield five frequency components. Nearly half of the total signal energy was carried in the first component, with the remaining four components, each carrying between 5-10% of the total original energy.

Freeman col 8 ln 28 – 41. Specifically, Freeman does not teach the collection of frequency bands comprising “delta (0.5-3.5 Hz), theta (3.5-7.5 Hz), alpha (7.5-12.5 Hz), and beta (12.5-35 Hz). *Applicants' Specification pg 11 ln 8-9.* Freeman clearly avoids collecting and analyzing EEG frequency bands that are elements in the Applicants' claimed embodiment.

The Applicants respectfully request the Examiner withdraw the rejection.

B. Freeman Does Not Provide Any Reasonable Expectation Of Success

The Examiner states that Freeman makes determining drug efficacy using EEG multivariate outcomes measurements obvious because:

Possible applications for the method disclosed by Freeman include ... using the signal to investigate the effects of drugs on certain mental states. Studies of this type enable one to establish drug dosage and duration parameters and/or pharmacokinetic or drug effects on certain behavioral activity (column 13, lines 15-68, column 14, lines 1-8).

¹ These disclosures are clear examples of “teaching away”.

Office Action, pg 6. The Applicants disagree because the paragraph cited by the Examiner is the only mention of “drug effects” within Freeman. This brief mention of “drug effects” within Freeman only provides a mere suggestion that must be interpreted as “obvious to try”. The Federal Circuit has made it clear that an obviousness rejection based upon the argument that something is "obvious to try" is a discredited and impermissible standard. *American Hospital Supply Corp. v. Travenol Laboratories, Inc.*, 745 F.2d 1, 223 USPQ 577 (Fed. Cir. 1984)("Of course, an 'obvious to try' standard is not a legitimate test of patentability."). Further, a reference must provide some direction as to how one having ordinary skill in the art would proceed to ensure success.

An invention is 'obvious to try' 'where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful.'

In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988). *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 10 USPQ 2d 1843, 1845 (Fed. Cir. 1989). Freeman does not provide any indication of which parameters are critical to determine drug efficacy.

C. No Motivation To Modify Freeman Is Presented

The Examiner has put forward only a single reference on which to support an obviousness rejection. The Examiner, therefore, tacitly admits that Freeman is not an anticipatory reference (i.e., it does not teach each and every element of the Applicants' claimed embodiment). Consequently, to create a *prima facie* case of obviousness the Examiner must find, within the general knowledge of those having ordinary skill in the art, the missing elements that would create the Applicants' claimed embodiment. Here, the Examiner has failed to present any extrinsic evidence that suggests Freeman should be modified.

Instead, the Examiner makes an unsupported and conclusory statement that:

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Freeman and generate a method of determining a drug effect by ... obtaining an EEG ... obtaining neurophysiologic information ... comparing the data prior to ... after administering the drug ...

Office Action pg. 6.

An Examiner is not permitted to make conclusions based upon knowledge concerning "one of ordinary skill in the art" unless proper evidence is provided (i.e., for example, a publication). The Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

The Examiner has the burden of showing that the cited art is justified by "evidence" which supplies a suggestion, teaching or motivation sufficient to provide one skilled in the art to create the Applicant's invention. This requirement is "an essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). There are three sources for this evidentiary component: the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). The suggestion most often comes from the teachings of the pertinent references. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Nonetheless, regardless of the source of the requisite evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements about the teaching of [a]... reference[], standing alone, are not 'evidence'." *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999).

For example, the Examiner has not shown that those having ordinary skill in the art would understand that Freeman's EEG signals could, or should, be decomposed into alpha, beta, delta, and theta frequency bands.

Consequently, the Applicants respectfully request the Examiner withdraw this rejection.

IV. The Claims Do Not Represent Double-Patenting

The Examiner states that "Claim 40 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 49 of copending Application No. 10/193,735". *Office Action* pg 3 ¶ 4. The Applicants respectfully inform the Examiner that Claim 49 within the '735 application has been canceled in response to a Restriction Requirement election (Mailed: December 5, 2005). Claims 1-28 (i.e., Group I) were elected to be prosecuted as the '735 application.

The Applicants respectfully request the Examiner withdraw this rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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